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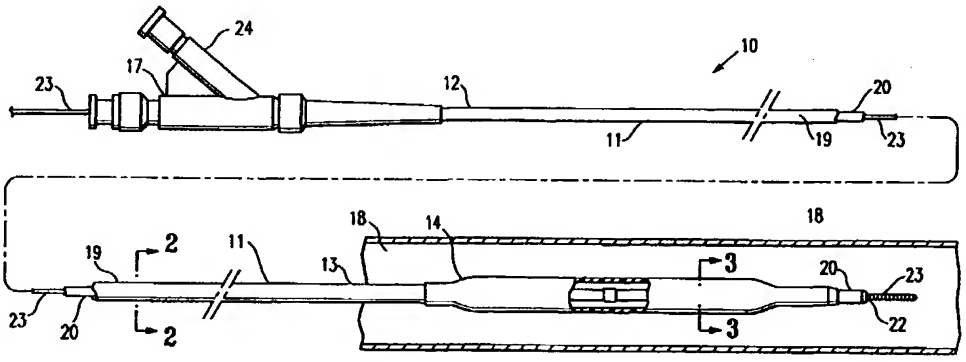

(57) Abstract

An inflatable member such as a ballon which is formed at least in part of a polyamide/polyether block copolymer thermoplastic elastomer, commonly referred to as polyether block amide (PEBA). The presently preferred PEBA copolymer is polyamide/polyether polyester copolymer, such as PEBAX®. The balloon of the invention exhibits high tensile strength, high elongation, and low flexural moduli. The balloon may be formed as a single layer of PEBA, or as a multilayer coextrudate having at least one PEBA layer. The balloon may be 100 % PEBA or a blend of PEBA with another polymer, such as nylon.

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POLYETHER BLOCK AMIDE CATHETER BALLOONS

BACKGROUND OF THE INVENTION

This invention generally relates to intravascular catheters, such as balloon dilatation catheters used in percutaneous transluminal coronary angioplasty (PTCA).

PTCA is a widely used procedure for the treatment of coronary heart disease. In this procedure, a balloon dilatation catheter is advanced into the patient's coronary artery and the balloon on the catheter is inflated within the stenotic region of the patient's artery to open up the arterial passageway and thereby increase the blood flow there through. To facilitate the advancement of the dilatation catheter into the patient's coronary artery, a guiding catheter having a preshaped distal tip is first percutaneously introduced into the cardiovascular system of a patient by the Seldinger technique through the brachial or femoral arteries. The catheter is advanced until the preshaped distal tip of the guiding catheter is disposed within the aorta adjacent the ostium of the desired coronary artery, and the distal tip of the guiding catheter is then maneuvered into the ostium. A balloon dilatation catheter may then be advanced through the guiding catheter into the patient's coronary artery until the balloon on the catheter is disposed within the stenotic region of the patient's artery. The balloon is inflated to open up the arterial passageway and increase the blood flow through the artery. Generally, the inflated diameter of the balloon is approximately the same diameter as the native diameter of the body lumen being dilated so as to complete the dilatation but not over expand the artery wall. After the balloon is finally deflated, blood flow resumes through the dilated artery and the dilatation catheter can be removed therefrom.

To reduce the restenosis rate and to strengthen the dilated area, physicians frequently implant an intravascular prosthesis, generally called a stent, inside the artery at the site of the lesion. Stents may also be used to repair vessels having an intimal flap or dissection or to generally strengthen a weakened section of a vessel. Stents are usually delivered to a desired location within a coronary artery in a contracted condition on a balloon of a catheter which is similar in many respects to a balloon angioplasty catheter, and expanded to a larger diameter by expansion of the balloon. The balloon is deflated to remove the catheter and the stent left in place

within the artery at the site of the dilated lesion. See for example, U.S. Pat. No. 5,507,768 (Lau et al.) and U.S. Pat. No. 5,458,615 (Klemm et al.), which are incorporated herein by reference.

One type of catheter frequently used in PTCA procedures is an over-the-wire type balloon dilatation catheter. When using an over-the wire dilatation catheter, a guidewire is usually inserted into an inner lumen of the dilatation catheter before it is introduced into the patient's vascular system and then both are introduced into and advanced through the guiding catheter to its distal tip which is seated within the ostium. The guidewire is first advanced out the seated distal tip of the guiding catheter into the desired coronary artery until the distal end of the guidewire extends beyond the lesion to be dilatated. The dilatation catheter is then advanced out of the distal tip of the guiding catheter into the patient's coronary artery, over the previously advanced guidewire, until the balloon on the distal extremity of the dilatation catheter is properly positioned across the lesion to be dilatated. Once properly positioned across the stenosis, the balloon is inflated one or more times to a predetermined size with radiopaque liquid at relatively high pressures (e.g., generally 4-12 atmospheres) to dilate the stenosed region of a diseased artery. After the inflations, the balloon is finally deflated so that the dilatation catheter can be removed from the dilated stenosis to resume blood flow.

Another type of dilatation catheter, the rapid exchange type catheter, was introduced by ACS under the trademark ACS RX® Coronary Dilatation Catheter. It is described and claimed in U.S. Patent 5,040,548 (Yock), U.S. Patent 5,061,273 (Yock), and U.S. Patent 4,748,982 (Horzewski *et al.*) which are incorporated herein by reference. This dilatation catheter has a short guidewire receiving sleeve or inner lumen extending through a distal portion of the catheter. The sleeve or inner lumen extends proximally from a first guidewire port in the distal end of the catheter to a second guidewire port in the catheter spaced proximally from the inflatable member of the catheter. A slit may be provided in the wall of the catheter body which extends distally from the second guidewire port, preferably to a location proximal to the proximal end of the inflatable balloon. The structure of the catheter allows for the rapid exchange of the catheter without the need for an exchange wire or adding a guidewire extension to the proximal end of the guidewire.

The perfusion type dilatation catheter is another type of dilatation catheter. This catheter, which can take the form of an over-the-wire catheter or a rapid exchange type catheter, has one or more perfusion ports proximal to the dilatation balloon in fluid communication with an guidewire receiving inner lumen extending to the distal end of the catheter. One or more perfusion ports are preferably provided in the catheter distal to the balloon which are also in fluid communication with the inner lumen extending to the distal end of the catheter. This provides oxygenated blood downstream from the inflated balloon to thereby prevent or minimize ischemic conditions in tissue distal to the catheter. The perfusion of blood distal to the inflated balloon allows for long term dilatations, e.g. 30 minutes or even several hours or more.

The balloons for prior dilatation catheters utilized in angioplasty procedures generally have been formed of relatively inelastic polymeric materials such as polyvinyl chloride, polyethylene, polyethylene terephthalate (PET), polyolefinic ionomers, and nylon. An advantage of such inelastic materials when used in catheter balloons is that the tensile strength, and therefore the mean rupture pressure, of the balloon is high. Catheter balloons must have high tensile strength in order to exert sufficient pressure on the stenosed vessel and effectively open the patient's passageway. Consequently the high strength balloon can be inflated to high pressures without a risk that the balloon will burst during pressurization. Similarly, the wall thickness of high strength balloons can be made thin, in order to decrease the catheter profile, without a risk of bursting.

Those inelastic materials having the least elasticity are also classified as "non-compliant" and "semi-compliant" materials, and include PET and nylon. Such non-compliant material exhibits little expansion in response to increasing levels of inflation pressure. Because the non-compliant material has a limited ability to expand, the uninflated balloon must be made sufficiently large that, when inflated, the balloon has sufficient working diameter to compress the stenosis and open the patient's passageway. However, a large profile non-compliant balloon can make the catheter difficult to advance through the patient's narrow vasculature because, in a uninflated condition, such balloons form flat or pancake shape wings which extend radially outward. Therefore, some compliance is desirable in an angioplasty

catheter balloon. Additionally, balloons formed of material with high compliance have increased softness, which improves the ability of the catheter to track the tortuous vasculature of the patient and cross the stenosis, to effectively position the balloon at the stenosis. The softness of a balloon is expressed in terms of the balloon modulus, where a relatively soft balloon has a relatively low flexural modulus of less than about 150,000 psi (1034 MPa).

Therefore, what has been needed is a relatively soft catheter balloon having a high rupture pressure. The present invention satisfies these and other needs.

SUMMARY OF THE INVENTION

The invention is directed to an inflatable member such as a balloon which is formed at least in part of a polyamide/polyether block copolymer thermoplastic elastomer, commonly referred to as polyether block amide (PEBA). The balloon of the invention exhibits high tensile strength, high elongation, and low flexural modulus.

A balloon catheter of the invention generally comprises a catheter having an elongated shaft with an inflatable balloon formed of PEBA thermoplastic elastomer on a distal portion of the catheter. Suitable PEBA balloon materials include, but are not limited to, PEBAX®, a polyamide/polyether polyester available from Atochem and described in U.S. Patents 4,331,786 and 4,332,920 (Foy et al.), which are incorporated herein by reference. The presently preferred PEBA copolymer is polyamide/polyether polyester copolymer.

The presently preferred balloon is formed from 100% PEBA. However, the balloon can be formed of a blend of PEBA with one or more different polymeric materials. Suitable polymeric materials for blending with PEBA include those polymers listed above used to make balloons for prior dilatation catheters, such as nylon. In a presently preferred embodiment, the balloon is a single polymeric layer. However, the balloon may also be multilayered, where the balloon is formed by coextruding two or more layers with one or more layers formed at least in part of PEBA.

Various designs for balloon catheters well known in the art may be used in the catheter of the invention having a balloon formed at least in part PEBA. For

example, the catheter may be a conventional over-the-wire dilatation catheter for angioplasty having a guidewire receiving lumen extending the length of the catheter shaft from a guidewire port in the proximal end of the shaft, or a rapid exchange dilatation catheter having a short guidewire lumen extending to the distal end of the shaft from a guidewire port located distal to the proximal end of the shaft. Additionally, the catheter may be used to deliver a stent mounted on the catheter balloon.

The balloon of the invention formed of PEBA thermoplastic elastomer, combines improved softness and tensile strength, to provide low profile balloon catheters having excellent ability to tract the patient's vasculature, cross the stenosis, and compress the stenosis to open the patient's vessel. These and other advantages of the invention will become more apparent from the following detailed description of the invention and the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an elevational view partially in section of the catheter of the invention showing the balloon in an unexpanded state.

Fig. 2 is a transverse cross sectional view of the catheter of Fig. 1 taken along lines 2-2.

Fig. 3 is a transverse cross sectional view of the catheter of Fig. 1 taken along lines 3-3.

Fig. 4 is an elevational view partially in section of the catheter of the invention.

Fig. 5 is a transverse cross sectional view of the catheter of Fig. 4 taken along lines 5-5.

DETAILED DESCRIPTION OF THE INVENTION

As shown in Fig. 1, the catheter 10 of the invention generally includes a an elongated catheter shaft 11 having a proximal section 12 and distal section 13, an inflatable balloon 14 formed at least in part of PEBA on the distal section 13 of the catheter shaft 11, and an adapter 17 mounted on the proximal section 12 of shaft 11 to direct inflation fluid to the interior of the inflatable balloon. Figs. 2 and 3 illustrate transverse cross sections of the catheter shown in Fig. 1, taken along lines 2-2 and 3-3 respectively.

In the embodiment illustrated in Fig. 1, the intravascular catheter 10 of the invention is an over-the-wire catheter, and is illustrated within a patient's body lumen 18 with the balloon 14 in an unexpanded state. The catheter shaft 11 has an outer tubular member 19 and an inner tubular member 20 disposed within the outer tubular member and defining, with the outer tubular member, inflation lumen 21. Inflation lumen 21 is in fluid communication with the interior chamber 15 of the inflatable balloon 14. The inner tubular member 20 has an inner lumen 22 extending therein, which is configured to slidably receive a guidewire 23 suitable for advancement through a patient's coronary arteries. The distal extremity of the inflatable balloon 14 is sealingly secured to the distal extremity of the inner tubular member 20 and the proximal extremity of the balloon is sealingly secured to the distal extremity of the outer tubular member 19.

The balloons of the invention are formed at least in part of polyamide/polyether block (PEBA) copolymers. The presently preferred PEBA copolymers have polyamide and polyether segments linked through ester linkages, i.e. polyamide/polyether polyesters. However, other linkages, such as amide linkages, can also be used. Polyamide/polyether polyester block copolymers are made by a molten state polycondensation reaction of a dicarboxylic polyamide and a polyether diol. The result is a short chain polyester made up of blocks of polyamide and polyether. The polyamide and polyether blocks are not miscible. Thus, the materials are characterized by a two phase structure having a thermoplastic region that is primarily polyamide and an elastomer region that is rich in polyether. The polyamide segments are semicrystalline at room temperature. The generalized

chemical formula for these polyamide/polyether polyester block copolymers may be represented by the following formula:

$$HO\text{–}(C\text{–}PA\text{–}C\text{–}O\text{–}PE\text{–}O)_n\text{–}H$$

(with the two C atoms double-bonded to O)

in which PA is a polyamide hard segment, PE is a polyether soft segment, and the repeating number n is between 5 and 10. The polyamide hard segment is a polyamide of C_6 or higher, preferably C_{10}-C_{12}, carboxylic acids; C_6 or higher, preferably C_{10}-C_{12}, organic diamines; or C_6 or higher, preferably C_{10}-C_{12}, aliphatic ω-amino-α-acids. The percentage by weight of the block copolymer attributable to the polyamide hard segments is between about 50% to about 95%. The polyether soft segment is a polyether of C_2-C_{10} diols, preferably C_4-C_6 diols. The block copolymer has a flexural modulus of less than about 150,000 psi (1034 MPa), preferably less than 120,000 psi (827 MPa).

The polyamide segments are suitably aliphatic polyamides, such as nylons 12, 11, 9, 6, 6/12, 6/11, 6/9, or 6/6. Most preferably they are nylon 12 segments. The polyamide segments may also be based on aromatic polyamides but in such case significantly lower compliance characteristics are to be expected. The polyamide segments are relatively low molecular weight, generally within the range of 500-8,000, more preferably 2,000-6,000, most preferably about 3,000-5,000. Another range which is of interest is 300-15,000.

The polyether segments are aliphatic polyethers having at least 2 and no more than 10 linear saturated aliphatic carbon atoms between ether linkages. More preferably the ether segments have 4-6 carbons between ether linkages, and most preferably they are poly(tetramethylene ether) segments. Examples of other polyethers which may be employed in place of the preferred tetramethylene ether segments include polyethylene glycol, polypropylene glycol, poly(pentamethylene ether) and poly(hexamethylene ether). The hydrocarbon portions of the polyether may be optionally branched. An example is the polyether of 2-ethylhexane diol. Generally such branches will contain no more than two carbon atoms. The molecular weight of the polyether segments is suitably between about 400 and

2,500, preferably between 650 and 1,000. Another range which is of interest is 200-6,000.

The weight ratio of polyamide to polyether in the polyamide/polyether polyesters used in the invention desirably should be in the range of 50/50 to 95/5, preferably between 60/30 and 92/08, more preferably, between 70/30 and 90/10.

Polyamide/polyether polyesters are sold commercially under the PEBAX trademark by Atochem North America, Inc., Philadelphia, PA. A suitable polymer grade for the intravascular balloon catheter of the invention is the PEBAX® 33 series. In the embodiment in which the balloon is 100% PEBA or a blend of PEBA and a polyamide, preferably PEBA and nylon, the presently preferred PEBAX® polymers have a hardness of Shore D durometer of at least about 60D, preferably between about 60D to about 72D, i.e. PEBAX® 6033 and 7233. In the embodiment in which the balloon is a coextruded multilayered balloon with at least one layer formed of PEBA, the presently preferred PEBAX® polymers have a hardness of Shore D durometer of at least about 35 D, preferably between about 35D to about 72D, i.e. PEBAX® 3533 and 7233.

The PEBAX® 7033 and 6333 polymers are made up of nylon 12 segments and polytetramethylene ether segments in about 90/10 and about 80/20 weight ratios, respectively. The average molecular weight of the individual segments of nylon 12 is in the range of about 3,000-5,000 grams/mole and of the polytetramethylene ether segments are in ranges of about 750-1,250 for the 6333 polymer and about 500-800 for the 7033 polymer. The intrinsic viscosities of these polymers are in the range of 1.33 to 1.50 dl/g. Generally speaking, balloons of PEBAX® 7033 type polymer exhibit borderline non-compliant to semi-compliant behavior and balloons of Pebax® 6333 type polymer show semi-compliant to compliant distention behavior, depending on the balloon forming conditions.

While the PEBAX®-type polyamide/polyether polyesters are most preferred, it is also possible to use other PEBA polymers with the physical properties specified herein and obtain similar compliance, strength and softness characteristics in the finished balloon.

The presently preferred PEBA material has an elongation at failure at room temperature of at least about 150%, preferably about 300% or higher, and an

ultimate tensile strength of at least 6,000 psi. The balloon has sufficient strength to withstand the inflation pressures needed to inflate the balloon and compress a stenosis in a patient's vessel. The burst pressure of the balloon is at least about 10 ATM, and is typically about 16-21 ATM. The wall strength of the balloon is at least about 15,000 psi (103 MPa), and typically from about 25,000 psi (172 Mpa) to about 35,000 psi (241 MPa).

As best illustrated in Fig. 3, the inflatable balloon 14 shown in Fig. 1 is formed of a single layer of polymeric material. The balloon may be 100% PEBA or a PEBA/polymer blend. The presently preferred polymer blend is a PEBAX®/nylon blend, and the preferred weight percent of nylon is from about 30% to about 95% of the total weight. The inflatable balloon 14 may also have multiple layers formed from coextruded tubing, in which one or more layers is at least in part formed from PEBA. In a presently preferred embodiment, the multilayered balloon is made from coextruded tubing have at least a nylon layer and a PEBA layer. The presently preferred PEBA is PEBAX®, and the presently preferred nylon is nylon 11, nylon 12, or blends thereof. The PEBAX® may be the inner layer or the outer layer of the balloon.

The balloon of the invention can be produced by conventional techniques for producing catheter inflatable members, such as blow molding, and may be preformed by stretching a straight tube before the balloon is blown. The balloons may be formed by expansion of tubing, as for example at a hoop ratio of between 3 and 8. The presently preferred PEBA balloon material is not crosslinked. The bonding of the balloon to the catheter may be by conventional techniques, such as adhesives and fusion with compatibilizers.

Fig. 2, showing a transverse cross section of the catheter shaft 11, illustrates the guidewire receiving lumen 22 and inflation lumen 21. The balloon 14 can be inflated by radiopaque fluid from an inflation port 24, from inflation lumen 21 contained in the catheter shaft 11, or by other means, such as from a passageway formed between the outside of the catheter shaft and the member forming the balloon, depending on the particular design of the catheter. The details and mechanics of balloon inflation vary according to the specific design of the catheter, and are well known in the art.

The length of the balloon 14 may be about 0.5 cm to about 6 cm, preferably about 1.0 cm to about 4.0 cm. After being formed, the balloon working length outer diameter at nominal pressure (e.g. 6-8 ATM) is generally about 0.15 cm to about 0.4 cm, and typically about 0.3 cm, although balloons having an outer diameter of about 1 cm may also be used. The single wall thickness is about 0.0004 inches (in) (0.0102 mm) to about 0.0015 in (0.0381 mm), and typically about .0006 in (0.0152 mm). In the embodiment in which the coextrusion balloon has two layers, the nylon layer single wall thickness is about .0003 in (0.0076 mm) to about .0006 in (0.0152 mm), and the PEBAX layer is about .0002 in (0.0051 mm) to about .0005 in (0.0127 mm).

Another embodiment of the invention is shown in Fig. 4, in which a stent 16 is disposed about the balloon 14 for delivery within patient's vessel. Fig. 5 illustrates a transverse cross section of the catheter shown in Fig. 4, taken along line 5-5. The stent 16 may be any of a variety of stent materials and forms designed to be implanted by an expanding member, see for example U.S. Patent 5,514,154 (Lau et al.) and 5,443,500 (Sigwart), incorporated by reference. For example, the stent material may be stainless steel, a NiTi alloy, a plastic material, or various other materials. The stent is shown in an unexpanded state in Fig. 4. The stent has a smaller diameter for insertion and advancement into the patient's lumen, and is expandable to a larger diameter for implanting in the patient's lumen. The balloon of the invention formed at least in part of PEBA has improved abrasion resistance, useful in stent delivery, due to the PEBA. In the embodiment of the invention in which the balloon has at least two coextruded layers, a balloon used for stent delivery preferably has the PEBA layer as the outer layer, to provide improved resistance to puncture by the stent. Additionally, the stent retention force is improved when the balloon is formed by coextrusion.

The following examples more specifically illustrate the invention.

EXAMPLE 1

PEBAX® 7033 was extruded into tubular stock having 0.035 in (0.889 mm) outer diameter (OD) and 0.019 in (0.483 mm) inner diameter (ID). The tubing was necked on one side at room temperature to ID of 0.018 in (0.457 mm). The tubing

was then made into 20 balloons using a glass mold at a temperature of 242 °F (116.7 °C) inside the mold and a blow pressure of 340 psi (2343 kPa). The balloons had an OD of 3 mm and a length of 20 mm. The balloon working length had a wall thickness of 0.0006 in (0.0152 mm) to 0.0007 in (0.0178 mm). The mean rupture pressure of the balloons was found to be 310 psi (2136 kPa) with a standard deviation of 17.21 psi (119 kPa).

EXAMPLE 2

PEBAX® 6033 and nylon 12 was coextruded into two layered tubing, with PEBAX® as the outer layer and nylon as the inner layer. The tubing had a 0.035 in (0.889 mm) OD and a 0.0195 in (0.495 mm) ID, and a nylon layer thickness of 0.004 in (0.102 mm) and a PEBAX® layer thickness of 0.002 (0.051 mm). The tubing was then made into 20 balloons using a glass mold as in Example 1, at a temperature of 235.5 °F (113 °C) inside the mold and a blow pressure of 300 psi (2067 kPa). The balloon working length had a wall thickness of 0.0005 in (0.0127 mm) to 0.00065 in (0.0165 mm). The mean rupture pressure of the balloons was found to be 317 psi (2184 kPa) with a standard deviation of 23.3 psi (161 kPa).

EXAMPLE 3

Twenty percent PEBAX® 7233 and 80% nylon 12 was blended in a single screw extruder, and extruded into tubular stock having 0.0325 in (0.826 mm) OD and 0.015 in (0.381 mm) ID. The tubing was then made into 10 balloons using a glass mold as in Example 1, at a temperature of 320 °F (160 °C) inside the mold and a blow pressure of 225 psi (1550 kPa). The balloon working length had a wall thickness of 0.00045 in (0.0114 mm). The mean rupture pressure of the balloons was found to be 280 psi (1929 kPa).

It will be apparent from the foregoing that, while particular forms of the invention have been illustrated and described, various modifications can be made without departing from the spirit and scope of the invention. For example, while the

balloon catheter illustrated in Fig. 1 has inner and outer tubular members with independent lumens, a single tubular membered shaft having two lumens therein may also be used. Other modifications may be made without departing from the scope of the invention.

WHAT IS CLAIMED IS:

1. A balloon for a medical device formed from a length of tubing of a polymer material by radial expansion of the tubing under pressure, the polymer material comprising a block copolymer thermoplastic elastomer characterized as follows:

the block copolymer is represented by the formula:

$$HO-(C-PA-C-O-PE-O)_n-H$$

(with the C atoms double-bonded to O)

in which PA is a polyamide hard segment of molecular weight in the range of 500-8,000;

PE is a polyether soft segment of molecular weight in the range of 500-2,500 and the repeating number n is between 5 and 10, the polyamide hard segments are polyamides of C_6 or higher carboxylic acids and C6 or higher organic diamines or of C_6 or higher aliphatic ω-amino-α-acids, and the polyether soft segments are polyethers of C_2-C_{10} diols;

the block copolymer has a flexural modulus of less than about 150,000 psi;

the block copolymer has a hardness, Shore D scale, of greater than 60; and

the percentage by weight of the block polymer attributable to the hard segments is between about 50% and about 95%.

2. A balloon as in claim 1 wherein the block copolymer segment, PA, is an aliphatic polyamide of one or more C_{10}-C_{12} aliphatic acids and one or more C_{10}-C_{12} aliphatic diamines or of a C_{10}-C_{12} aliphatic ω-amino-α-acid.

3. A balloon as in claim 1 wherein the polyamide segment, PA, is selected from the group consisting of nylon 12, nylon 11, nylon 9, nylon 6, nylon 6/12, nylon 6/11, nylon 6/9 and nylon 6/6.

4. A balloon as in claim 1 wherein the polyamide segment, PA, is nylon 12 of a molecular weight of 3,000-5,000, and the polyether segment, PE, is poly(tetramethylene ether) of molecular weight between 500 and 1250.

5. A balloon as in claim 1 wherein the polyamide segments, PA, comprise between 80 and 90% by weight of the polyamide/polyether polyester.

6. A balloon as in claim 1 wherein said polyether segment, is selected from the group consisting of poly(tetramethylene ether), poly(pentamethylene ether) and poly(hexamethylene ether).

7. A balloon as in claim 1 wherein the wall strength of the balloon is at least 15,000 psi.

8. A balloon as in claim 7 wherein the wall thickness, single wall basis, is no more than 0.0015 inches and said wall strength is greater than 18,000 psi.

9. A balloon as in claim 8 wherein said wall thickness is no more than 0.0009 inches.

10. A balloon as in claim 7 wherein said wall strength is greater than 20,000 psi.

11. A balloon as in claim 1 wherein the polymer material forming the tubing further comprises a second polymer blended with the block copolymer thermoplastic elastomer.

12. The balloon as in claim 11 wherein the second polymer is nylon.

13. The balloon as in claim 12 wherein the nylon is selected from the group consisting of nylon 11 and nylon 12.

14. The balloon as in claim 13 wherein the percentage by weight of the nylon is about 30% to about 95%.

15. The balloon as in claim 13 wherein the block copolymer thermoplastic elastomer has a hardness of Shore D durometer of about 60D to about 72 D.

16. A balloon for a medical device, comprising

a) a first polymeric layer; and

b) at least a second polymeric layer coextruded with the first layer, comprising a block copolymer thermoplastic elastomer represented by the formula:

$$HO\text{–}(C\text{–}PA\text{–}C\text{–}O\text{–}PE\text{–}O)_n\text{–}H$$

(with the two C atoms each double-bonded to an O)

in which PA is a polyamide hard segment of molecular weight in the range of 500-8,000;

PE is a polyether soft segment of molecular weight in the range of 500-2,500 and the repeating number n is between 5 and 10, the polyamide hard segments are polyamides of C_6 or higher carboxylic acids and C6 or higher organic diamines or of C_6 or higher aliphatic ω-amino-α-acids, and the polyether soft segments are polyethers of C_2-C_{10} diols;

the block copolymer has a flexural modulus of less than about 150,000 psi;

the block copolymer has a hardness, Shore D scale, of greater than 30; and

the percentage by weight of the block polymer attributable to the hard segments is between about 50% and about 95%.

17. The balloon as in claim 16 wherein the first polymeric layer comprises nylon.

18. The balloon as in claim 17 wherein the nylon is selected from the group consisting of nylon 11 and nylon 12.

19. The balloon as in claim 18 wherein the block copolymer thermoplastic elastomer has a hardness of Shore D durometer of about 35D to about 72 D.

20. An intravascular catheter, comprising:

a) an elongated catheter shaft having a proximal end, a distal end, and a lumen extending therein; and

b) an inflatable member on the distal end of the catheter shaft having an interior in fluid communication with the lumen of the catheter shaft, and being formed from a polyether/polyamide polyester block copolymer having a flexural modulus of less than about 150,000 psi.

21. The intravascular catheter of claim 20 further including a stent disposed about the inflatable member.

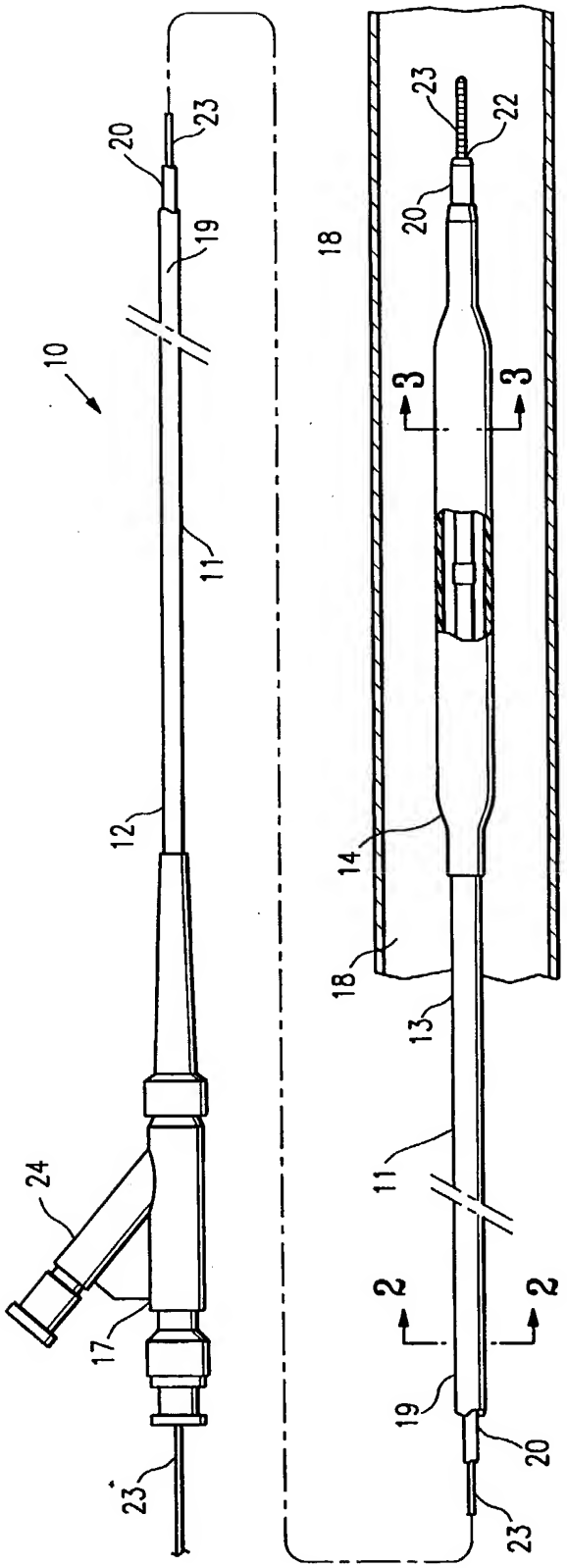

FIG. 1

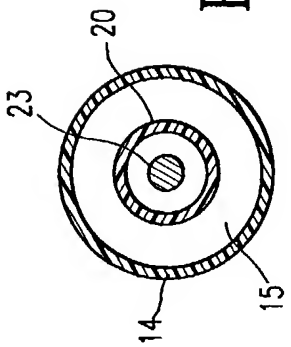

FIG. 3

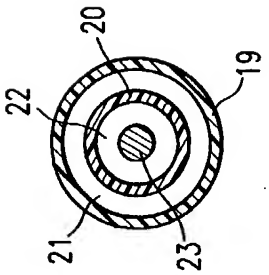

FIG. 2

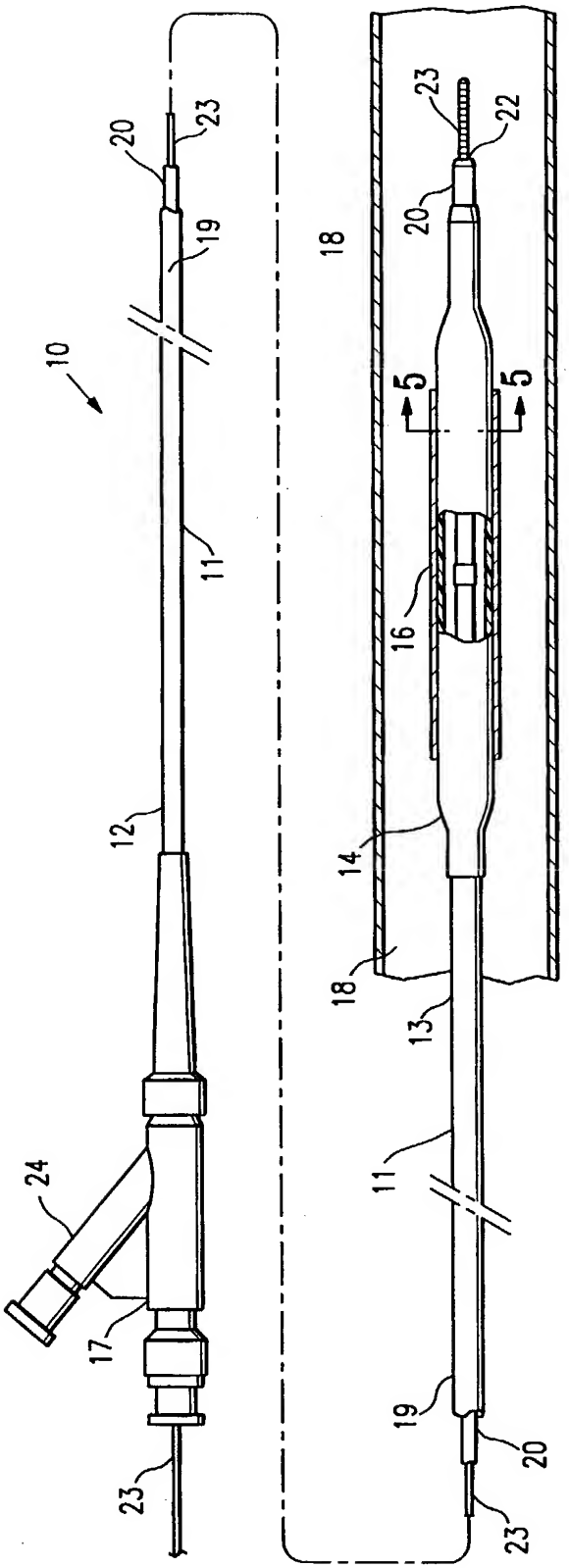

FIG. 4

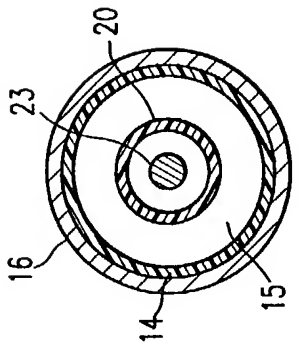

FIG. 5